

REMARKS

Claim 1 is amended to specify that each of the spherical, articular surfaces is a section of a sphere, which finds support on page 4, lines 26-27 of the description. Claim 1 is further amended to recite that the disk is a graphite core coated with wear-resistant pyrocarbon, support for which is found on page 7, lines 6-13 of the description. Claim 9 is amended to recite that the integral disk has a modulus of elasticity similar to that of cortical bone, support for which is found on page 7, lines 11-12 of the description. Support for the amendment to claim 16 is found in original claim 18.

Amended claim 1 would not be anticipated by the disclosure of U.S. Patent No. 7,004,971 to Serhan (hereinafter Serhan). Serhan teaches an elastic disk of circular shape which has a large central cavity that includes a circular opening (Fig. 4) or may be closed by a thin web to provide split recesses 131,133 (Fig. 13). It is formed of material such as polyurethane, which is compressible, i.e. compressing under an axial load, and resilient so as to regain its original shape when unloaded (see column 3, lines 57-61). The Figures 13 and 14 embodiments thus each embody a central concave surface surrounded by a toroidal rim. The device is made of an elastomeric material so that it can be folded in half and slid into a minimally invasive tube to be pushed through a small window to enter the disk space. It does not serve to provide articulation between two complementary bone surfaces. Instead, it is designed to provide cushioning and support in an axial direction by axially compressing and expanding radially to press against the inner surface of the natural annular wall within the spine and transfer load (see, for example, column 6, lines 45-54).

Amended claim 1 defines a biarticular disk, which is a graphite core coated with wear-resistant pyrocarbon, and which provides sliding support for the articular surface of the respective bone of the patient, e.g. the metacarpus and the trapezium. These convex surfaces are defined as sections of a spherical surface. In contrast, Serhan shows a large concave central cavity surrounded by a toroidal rim. There are no oppositely facing convex articular surfaces in the form of sections of a spherical surface. The Serhan device would have only contact with a concave spherical surface of a bone along a circular line. Most importantly, there is no intention to provide any articular surface, for the Serhan device is designed to provide support against axial compression and upon loading to spread to redistribute the load as a result of its elastomeric character. It is submitted that amended claim 1 is clearly not anticipated by Serhan, and the rejection under 35 U.S.C. § 102 should be reconsidered and withdrawn.

Amended claim 9 defines a biarticular disk having a pair of convex articular surfaces, each of which is a section of a sphere and which is made of a material having a modulus of elasticity similar to that of cortical bone. This is in contrast to the elastomeric device which would be totally inappropriate for disposition between two articulating bones if one desired to provide two sliding interfaces; it is designed solely to accept axial compression, not relative sliding movement, and to deform to redistribute the axially applied load. Accordingly, it is submitted that amended claim 9 is likewise not anticipated by the disclosure of Serhan, and its rejection under 35 USC § 102 should be reconsidered and withdrawn.

With respect to the Examiner's Section 103 rejection of certain of the dependent claims as being obvious over Serhan, mention is made of one having ordinary skill in the art providing

strength to resist axial compressive forces. However, such is the purpose of Serhan, not of Applicant's biarticular disk. The purpose of Applicant's biarticular disk is to provide two oppositely facing, convex, articular surfaces which will interface in sliding contact with complementary spherical concave surfaces created in two bones which articulate one against the other, such as the metacarpus and the trapezium and which has a central opening of such a design that the bones can move relative to each other while a flexible cord threaded through this opening is subjected to minimal undesired stretching at the point where it bears against the toroidal interior surface that forms each opposite edge of the disk central opening. This function is enunciated at page 6, line 19 through page 7, line 1, which reads as follows:

"This combination of the biconvex disk face surfaces and the toroidal flaring axial hole allows the metacarpus to easily flex, moving relative to the trapezium sufficiently to effect useful hand function, with each bone sliding on its respective, mating convex surface of the disk, while a flexible cord passing through the axial opening 13 follows and conforms to the portion of the toroidal surface of the axial opening in the plane of flexion. This design, which facilitates such relative motion between implant and bone surfaces, maximizes the range of joint flexion while minimizing the amount of stretching force that is being applied to the flexible cord passing through the implant because the effective center of bending will no longer be at the edge of the rim of the implant as a result of such relative shifting of the implant. Moreover, the toroidal shape of the flaring opening against which the flexible cord, preferably a harvested tendon, bears significantly minimizes undesired stretching at this location."

Support against axial compression is the purpose of Serhan but definitely not the purpose of Applicant's biarticular disk.

The subject matter defined in amended claim 7, amended claim 15 and amended claim 16 would not be obvious under 35 U.S.C. § 103(a) in view of the disclosure of U.S. Patent No. 5,888,203 to Goldberg (hereinafter Goldberg) in view of published U.S. Application No.

2003/0093152 to Pedersen (hereinafter Pedersen). Goldberg, as pointed out in its abstract, replaces a bone with a prosthesis and restrains the implant along two crisscrossing axes. As the Examiner points out in paragraph 15, Goldberg does disclose creating a cavity in the metacarpus and a cavity in the trapezium. However, these cavities are not articular surfaces; they are cavities which respectively receive, in "interference fit", a hemi-trapezium component 126 and a metacarpal base component 128 that can be optionally cemented in place. It is these two inserts that then articulate against each other. Each of these inserts is respectively restrained by a pair of crisscrossing ligament means. Ligament means 130 and 132 pass through the trapezium insert 126 and are attached to surrounding ligaments or the like. Similarly, two ligament means 134 and 136 pass through the metacarpal base insert 128 and are likewise respectively attached to appropriate surrounding ligaments. It is submitted that careful study of Goldberg will show that the focus is upon using pairs of ligament means which are routed in crisscrossing directions to restrain an inserted component by attachment to surrounding ligaments or the like. There is nothing in Goldberg that would teach one to create two facing, concave articular surfaces in two bones (such as the metacarpus and the trapezium), to insert a biarticular implant into the open region created by such resection, and to also provide a passageway in each of the bones (the trapezium and the metacarpus) opening into the center of that concave articular surface through which a flexible cord is passed which is routed through the carefully designed, central opening through the biarticular disk.

There is nothing in Pedersen which would suggest modifying the implants of Goldberg, which are designed to accept the passage of ligament means in two crisscrossing directions, to arrive at Applicant's claimed invention.

Pedersen shows a cushioning device that is designed to be inserted when there is cartilage damage or the like. It is, in essence, an elastic cushion. The device is made of a resilient elastomeric material such as high consistency elastomers, rubbers and polymers such as polyolefins (see paragraphs 95-97). Preferred polymers are set forth in paragraphs 123-137. The device must be able to deform to the irregular shape required to fill the gap between the two facing bones where damage has occurred (see paragraph 150). To install the device, it is provided with a slit such as the slit 32, 36 or 41, in Figures 7, 9 and 11, which allows the device to be inserted so as to surround an intact ligamentum femoris 5 (see Figure 2, paragraph 245).

It is submitted that this deformable cushioning device that serves as a cartilage replacement and deforms to an irregular shape, as depicted in Figure 3 for example, would in no way be suggestive of Applicant's employment of a biarticular disk of pyrocarbon-coated graphite, the hard, wear-resistant surfaces of which provide two replacement sets of articulation surfaces that supplant the original articulation arrangement between, for example, the trapezium and the metacarpus. The collapsible cushion shown in Figure 14 has two surfaces that happen to be frustoconical in shape, i.e. each a section of a surface of a cone as evidenced by the straight lines shown in the cross-sectional view. However, the original shape of this elastomeric cushion is of little importance (witness the variety of shapes shown in Figs. 6 to 28), because its only purpose and function is to deform and replace the cartilage that is shown missing in Figure 2.

The deformed device 11 is shown in Fig. 3. The installation of a representative such device 11 is depicted in Figures 4 and 5. Once the device 11 is installed, the bones approach each other, and the device 11 deforms to fill the irregular gap (seen in Fig. 2), as depicted in Figure 3.

It is submitted that, upon reflection, it can be seen that we are here viewing two totally different concepts. Pedersen would replace damaged cartilage with an elastomeric insert that would deform into a reduced volume or a slender shape to either replace or supplement worn or damaged cartilage in a joint (see, for example, claims 37 and 55). This is an opposite approach to that taken by Applicant's invention. Applicant resects the ends of two articulating bones and creates therein two concave spherical articular surfaces. The gap created is then filled by Applicant's novel biarticular disk, which is held in place via a flexible cord, likely a harvested tendon, that is threaded through the axially extending flaring hole in the biarticular disk and through passageways created respectively in the two bones, which passageways extend centrally into the concave spherical articular surfaces formed in the respective bones. The two approaches are essentially directly opposite ways of solving a somewhat similar problem. Accordingly, Pedersen, when fairly viewed, is a teaching directly away from Applicant's concept of using a hard, biarticular disk, with oppositely disposed articular surfaces which are sections of a sphere and which slide upon the interfacing concave articular surfaces created in the respective bones. Accordingly, such an attempted combination with Pedersen, which teaches away from Applicant's inventive concept, is improper; the rejection under § 103 for such a combination of references should be reconsidered and withdrawn.

With respect to paragraph 18 of the Office Action and the Examiner's observations with respect to Goldberg et al, it is pointed out that careful consideration of the paragraph bridging columns 10 and 11 of Goldberg et al, together with Figure 10, show that the two passageways created in the trapezium crisscross each other, i.e. the ligament means 130,132 extend laterally through the implanted insert and are attached to surrounding ligaments or the like. Neither passes through the articular surface which the insert 126 provides. There is no flexible cord extending from a passageway in the trapezium insert to a passageway in the base metacarpus insert. The ultimate articulating surfaces are the solid surfaces provided respectively by the two inserts, which interface with each other. In addition to being interference-fit or cemented in the respective bones, the inserts are each restrained by crisscrossing, laterally oriented ligament means.

With respect to paragraph 21 of the Office Action, it is pointed out that the portion of the description (to which attention is called) is directed to the circular perimeter of the Serhan device. The outer surface to which reference is made is that of the radial periphery of the device, which surface can optionally be flat, such as the outer surface 21 in Figure 1 (see column 3, lines 62-63).

Moreover, the Examiner is in error in stating that the biarticular disk shown and claimed in the instant application "cushions" finger bones. The disk is a hard object which provides two wear-resistant articular surfaces; each is a section of a sphere and slides against bone. There is no cushioning involved. It is a replacement of a single pair of articular surfaces, i.e. in the original

interface between two bones, with two sets of articular interfaces, one articular surface of each set being provided by the opposite surfaces of the hard biarticular disk.

Pursuant to the foregoing remarks, it is submitted that amended claims 1, 9, and 16 are neither anticipated by Serhan nor obvious in view of the teachings of Goldberg and Pedersen. Accordingly, it is believed that the rejections should be withdrawn and that these three independent claims, together with the claims dependent thereupon, should be allowed. In the absence of more pertinent prior art, it is believed that this application has been placed in condition for allowance, and issuance of a Notice of Allowance is courteously solicited.

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